DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#17

Food and Drug Administration
Rockville MD 20857

Re: Frova
Docket No.: 03E-0147

JAN 15 2004

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,464,864 and 5,616,603 filed by Vernalis, Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Frova, the human drug product claimed by the patents.

The total length of the regulatory review period for Frova is 2,201 days. Of this time, 1,186 days occurred during the testing phase and 1,015 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 1, 1995.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 1, 1995.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: January 29, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Frova (NDA 21-006) was initially submitted on January 29, 1999.

3. The date the application was approved: November 8, 2001.

   FDA has verified the applicant's claim that NDA 21-006 was approved on November 8, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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